I

104TH CONGRESS
1ST SESSION

H. R. 1735

To amend the Public Health Service Act with respect to research regarding the health of children.

IN THE HOUSE OF REPRESENTATIVES

MAY 25, 1995

Mr. MORAN (for himself, Mr. SERRANO, Mr. ACKERMAN, Mr. SCOTT, Mr. COYNE, Mr. UNDERWOOD, Mr. MASCARA, Mr. MILLER of California, Mr. RICHARDSON, Mr. ANDREWS, Mr. THORNTON, Mr. HILLIARD, Mr. DELLUMS, Mr. PETE GEREN of Texas, Mr. HASTINGS of Florida, Mr. PETERSON of Florida, Ms. LOFGREN, Mrs. MALONEY, Mr. MCDERMOTT, Mr. BENTSEN, Mr. FAZIO of California, Mr. WOLF, Mrs. MORELLA, Mr. DAVIS, Mr. GEKAS, Mr. NETHERCUTT) introduced the following bill; which was referred to the Committee on Commerce

---

A BILL

To amend the Public Health Service Act with respect to research regarding the health of children.

Be it enacted by the Senate and House of Representatives of the United States of America in Congress assembled,

SECTION 1. SHORT TITLE.

This Act may be cited as the ''Pediatric Research Initiative Act of 1995''.

SEC. 2. FINDINGS.

The Congress finds as follows:

(1) The savings from biomedical and behavioral research is significant due to the potential years of productive life saved, and to improvements in the quality of life for children and their families.

(2) The opportunities for biomedical advancements are greater than ever, given the enormous growth in knowledge and developments in genetics, immunology and related therapies.

(3) Childhood cancer is the leading medical cause of death in children ages 1 through adolescence; the incidence of childhood cancer is increasing; and a number of childhood cancers have not yielded to research.

(4) The average age of onset of cancer in children is 6 years; for adults, it is 67 years. The potential to save a lifetime of productive years by investing in pediatric research is not adequately reflected in the current allocation of Federal research dollars.

(5) Unintentional injuries are the number one killer of children ages 14 and under, and cost society $13,800,000,000 annually. Investment in childhood injury prevention can save billions of dollars as well as save children and their families needless pain and suffering.

(6) Biomedical, behavioral and injury prevention research which focuses on the unique needs of children receive far less funding than similar research for any other demographic group, including for men, seniors, women and minorities.

(7) The goal of the Pediatric Research Initiative is to ensure that these opportunities to significantly improve the identification, treatment, cure, and, ultimately, prevention of diseases, disabilities, and injuries that affect children are realized.

TITLE I—BIOMEDICAL AND BEHAVIORAL RESEARCH

SEC. 101. INTERAGENCY PLAN FOR PEDIATRIC RESEARCH.

Part B of title IV of the Public Health Service Act (42 U.S.C. 284 et seq.) is amended by adding at the end the following section:

''PEDIATRIC RESEARCH INITIATIVE

''SEC. 409B. (a) IN GENERAL.—

''(1) INTERAGENCY PLAN.—The Director of NIH shall establish a comprehensive plan for the conduct and support by the national research institutes of pediatric research, and shall periodically review and as appropriate make revisions in the plan. The Director of NIH shall carry out this section in collaboration with the Director of the National Institute of Child Health and Human Development.

''(2) CONSULTATIONS WITH INSTITUTE DIRECTORS.—In carrying out this section, the Director of NIH shall consult with the directors of each of the national research institutes.

''(3) ADVISORY COUNCIL.—

''(A) The Secretary shall establish an advisory council to be known as the National Advisory Council on Pediatric Research (in this paragraph referred to as the 'Advisory Council').

''(B) The Advisory Council shall provide advice to the Secretary and the Director of NIH regarding the Plan. In carrying out the preceding sentence, the advisory council shall develop and submit to the Director proposals regarding the contents of the Plan.

''(C)(i) Subject to clause (ii), the Secretary shall appoint to the Advisory Council, as voting members, not more than 15 individuals. Such individuals shall be appointed from among individuals who are not officers or employees of the Federal Government.

''(ii) The Secretary shall ensure that, collectively, the members of the Advisory Council who are appointed under clause (i) have exper-

tise in epidemiology, biomedical research, behavioral research, basic research, clinical research (including the conduct of clinical trials), and biomedical ethics. The individuals appointed under such clause shall include one practicing pediatrician and one individual representing the interests of pediatric patients and the families of such patients.

''(D) The ex officio, nonvoting members of the Advisory Council shall be the following:

''(i) The Director of the National Institute of Child Health and Human Development.

''(ii) The Directors of each of the national research institutes whose principal responsibilities include the conduct and support of pediatric research.

''(iii) The Commissioner of Food and Drugs.

''(E) The Secretary shall designate a member of the Advisory Council to serve as the chair of the Council.

''(b) GENERAL REQUIREMENTS FOR PLAN.—

''(1) IDENTIFICATION OF RELEVANT PROJECTS.—In developing, reviewing, and revising

the Plan, the Director of NIH shall identify the projects of pediatric research that are being conducted or supported by the national research institute, and current proposals for such projects.

''(2) GENERAL REQUIREMENTS; CATEGORIES OF RESEARCH.—The Director shall ensure that the Plan specifies the following with respect to pediatric research:

''(A) The categories of research that are to be conducted and supported by the National Institutes of Health.

''(B) Priorities among such categories.

''(C) The areas in which an insufficient number or variety of projects have been conducted or supported by such Institutes, and the areas in which the activities of the national research institutes are overlapping.

''(D) The process for coordinating research activities among the national research institutes.

''(E) Promising areas in which the National Institutes of Health will conduct or support research.

''(F) In the case of the research priorities specified under subparagraph (B), mechanisms

to encourage public and private entities to initiate research independently of solicitations by the National Institutes of Health for proposals.

''(G) Objectives for the research conducted or supported under the Plan, the means for achieving the objectives, and the date by which the objectives are expected to be achieved.

''(3) PARTICULAR PROJECTS.—In carrying out paragraph (2) with respect to a category of research, the Director of NIH may establish requirements regarding particular projects of research within a category.

''(c) CERTAIN CONSIDERATIONS.—In developing, reviewing, and revising the Plan, the Director of NIH shall consider the following with respect to children:

''(1) Epidemiological data, including the incidence and prevalence of various causes of death or disability.

''(2) The severity of various diseases and the impact of the diseases on functional capacity.

''(3) The potential for significant progress in the diagnosis, treatment, prevention, and control of various diseases, disorders, and disabilities.

''(d) CERTAIN COMPONENTS OF PLAN.—The Director of NIH shall ensure that the Plan provides for an appropriate emphasis on the following:

''(1) Evaluations of the results of basic research in order to develop and commence projects of clinical research.

''(2) The support of proposals developed pursuant to solicitations by the national research institutes, and the support of proposals developed independently of such solicitations.

''(3) The support of proposals for projects whose principal researchers will be individuals who have not previously served as the principal researchers of projects supported by the national research institutes.

''(4) Both biomedical research and behavioral research.

''(e) DATES CERTAIN REGARDING APPLICABILITY OF PLAN; INITIAL REVIEW.—The initial Plan shall be developed and shall take effect not later than October 1, 1996. The initial review of the Plan under subsection (a)(1) shall be completed not later than October 1, 1998, and a review shall be conducted not less than once during each subsequent two-year period.

''(f) ANNUAL REPORT.—Not later than February 1 of each fiscal year, the Director of NIH shall submit to the Committee on Commerce and the Committee on Appropriations (of the House of Representatives), and to the Committee on Labor and Human Resources and the Committee on Appropriations (of the Senate), a report describing the activities undertaken and expenditures made under this section during the preceding fiscal year. The report may contain such comments of the Director of NIH regarding this section as the Director determines to be appropriate.

''(g) DEFINITIONS.—For purposes of this section:

''(1) The term 'pediatric research' means biomedical and behavioral research regarding the health of children.

''(2) The term 'Plan' means the plan established, reviewed, and revised under subsection (a)(1).

''(h) AUTHORIZATION OF APPROPRIATIONS.—For the purpose of carrying out this section, there are authorized to be appropriated $60,000,000 for fiscal year 1996, $75,000,000 for fiscal year 1997, $100,000,000 for fiscal year 1998, and such sums as may be necessary for fiscal year 1999 and each subsequent fiscal year.''.

SEC. 102. INCLUSION OF CHILDREN IN CLINICAL RESEARCH.

Part H of title IV of the Public Health Service (42 U.S.C. 289 et seq.) is amended by inserting after section 492B the following section:

''INCLUSION OF CHILDREN IN CLINICAL RESEARCH

''SEC. 492C. (a) IN GENERAL.—The Director of NIH shall establish guidelines regarding the inclusion of children as subjects in projects of clinical research conducted or supported by the National Institutes of Health.

''(b) CERTAIN CONSIDERATIONS.—In establishing guidelines under subsection (a), the Director of NIH shall consider—

''(1) the principles applied under section 492B by the Director in including women and members of minority groups as subjects in projects of clinical research; and

''(2) the factors underlying the plan developed under section 409B (relating to the conduct and support of pediatric research).

''(c) INCREASE REGARDING INCLUSION OF CHILDREN.—

''(1) INCREASE REGARDING FISCAL YEAR 1998.—The Director of NIH shall ensure that, for fiscal year 1998, the child-subject percentage is sig-

nificantly increased above such percentage for fiscal year 1995.

''(2) CHILD-SUBJECT PERCENTAGE.—For purposes of this section, the term 'child-health percentage', with respect to a fiscal year, means the percentage constituted by the ratio of—

''(A) the number of children who, during the fiscal year, participated as subjects in projects of clinical research conducted or supported by the National Institutes of Health; to

''(B) the number of individuals (adults and children) who, during the fiscal year, participated as such subjects.''.

TITLE II—PREVENTIVE HEALTH RESEARCH

SEC. 201. INTERAGENCY PLAN FOR PEDIATRIC RESEARCH; DISCRETIONARY FUND.

Title III of the Public Health Service Act (42 U.S.C. 241 et seq.) is amended by adding at the end the following part:

''PART O—PREVENTIVE HEALTH RESEARCH REGARDING CHILDREN

"SEC. 399M. RESEARCH REGARDING CHILDREN AND PREVENTABLE DISEASES, DISORDERS, AND INJURIES.

''(a) IN GENERAL.—The Secretary shall carry out a program of research regarding preventable diseases, disabilities, and injuries in children, including research on the causes of death in children. The Secretary may conduct the research directly or through making grants to public and nonprofit private entities.

''(b) COLLABORATION WITH RELEVANT AGENCY HEADS.—The Secretary shall carry out subsection (a) in collaboration with the following:

''(1) The Director of the Centers for Disease Control and Prevention.

''(2) The Director of the National Institute of Child Health and Human Development.

''(3) The Director of the National Center for Injury Prevention and Control.

''(4) The Director of the Maternal and Child Health Bureau.

''(5) The Administrator for Health Care Policy and Research.

''(6) Such other Federal officials as the Secretary determines to be appropriate.

''(c) ADVISORY COMMITTEE.—

''(1) IN GENERAL.—The Secretary shall provide for a committee to provide advice to the Secretary regarding pediatric prevention research. The members of the committee shall be appointed from individuals who have expertise in pediatric prevention activities and who, subject to paragraph (2), are not officers or employees of the Federal Government.

''(2) USE OF EXISTING COMMITTEES.—A Federal employee may serve as a member of the advisory committee under paragraph (1) if the only Federal duty of the employee is to serve on one or more Federal advisory committees, and if the individual, when first appointed to such a committee, was not a Federal officer or employee.

''(d) INTERAGENCY PLAN.—The Secretary—

''(1) shall establish a comprehensive plan for carrying out subsection (a) through the Centers for Disease Control and Prevention and such other agencies of the Department as the Secretary determines to be appropriate; and

''(2) shall periodically review and as appropriate make revisions in the plan.

''(e) GENERAL REQUIREMENTS FOR PLAN.—

''(1) PRELIMINARY EVALUATIONS.—

''(A) In developing, reviewing, and revising the Plan, the Secretary shall—

''(i) identify and evaluate projects of pediatric prevention research that are being carried out through the agencies of the Department, and proposals for such projects; and

''(ii) to the extent practicable, identify and evaluate the projects of pediatric prevention research that are being carried out through other public or private entities, and proposals for such projects.

''(B) The projects identified and evaluated by the Secretary under subparagraph (A) shall include the following:

''(i) Demonstration projects that provide training in the prevention of injuries in children.

''(ii) Demonstration projects that develop curricula for such training for use in the training of health professionals who routinely provide care for children, including such professionals in the fields of pub-

lic health, medicine, nursing, dentistry, and allied health (including emergency medical technicians).

''(iii) Demonstration projects that develop curricula for such training for use in the training of parents, teachers, day-care personnel, and other individuals who routinely supervise children.

''(2) GENERAL REQUIREMENTS; CATEGORIES OF RESEARCH.—The Secretary shall ensure that the Plan specifies the following with respect to pediatric prevention research:

''(A) The categories of research that are to be conducted and supported by the Department.

''(B) The allocation among such agencies of responsibilities for the categories designated under subparagraph (A).

''(C) Priorities among such categories.

''(D) Objectives for the research conducted or supported under the Plan, the means for achieving the objectives, and the date by which the objectives are expected to be achieved.

''(E) The process for coordinating and consolidating research activities among the agencies of the Department.

''(3) PARTICULAR PROJECTS.—In carrying out paragraph (2) with respect to a category of research, the Secretary may establish requirements regarding particular projects of research within a category.

''(f) CERTAIN CONSIDERATIONS.—In developing, reviewing, and revising the Plan, the Secretary shall consider the following with respect to children.

''(1) Epidemiological data, including the incidence and prevalence of various causes of death or disability.

''(2) The severity of various diseases and injuries and the impact of such diseases and injuries on functional capacity.

''(3) The potential for significant progress in the prevention of various diseases, disabilities, and injuries.

''(g) MODEL PROGRAMS FOR SUPERVISORS OF CHILDREN.—With respect to parents, teachers, and other individuals who routinely supervise children, the Secretary shall ensure that the Plan provides for the development of model programs for educating such individuals on pediatric prevention activities.

''(h) DATES CERTAIN REGARDING APPLICABILITY OF PLAN; INITIAL REVIEW.—The initial Plan shall be developed and shall take effect not later than October 1, 1996.

The initial review of the Plan under subsection (d)(2) shall be completed not later than October 1, 1998, and a review shall be conducted not less than once during each subsequent two-year period.

''(i) DISCRETIONARY FUND.—

''(1) IN GENERAL.—There is established a fund to be known as the Pediatric Prevention Research Initiative Fund, consisting of such amounts as may be appropriated under subsection (l) for the Fund.

''(2) USE OF FUND.—Amounts in the Fund are available to the Secretary for such activities regarding pediatric prevention research as are authorized under this Act, including activities under the Plan.

''(j) ANNUAL REPORT.—Not later than February 1 of each fiscal year, the Secretary shall submit to the Committee on Commerce and the Committee on Appropriations (of the House of Representatives), and to the Committee on Labor and Human Resources and the Committee on Appropriations (of the Senate), a report describing the activities undertaken and expenditures made under this section during the preceding fiscal year, including with respect to the Fund. The report may contain such comments of the Secretary regarding this section as the Secretary determines to be appropriate.

''(k) DEFINITIONS.—For purposes of this section:

''(1) The term 'Department' means the Department of Health and Human Services, unless the context of usage indicates otherwise.

''(2) The term 'Fund' means the fund established in subsection (i)(1).

''(3) The term 'pediatric prevention activities' means activities for the prevention of diseases, disabilities, and injuries in children.

''(4) The term 'pediatric prevention research' means research described in subsection (a).

''(5) The term 'Plan' means the plan established, reviewed, and revised under subsection (d).

''(l) AUTHORIZATION OF APPROPRIATIONS.—For the purpose of carrying out this section, there are authorized to be appropriated $30,000,000 for fiscal year 1996, $30,500,000 for fiscal year 1997, and $50,000,000 for fiscal year 1998.''.

TITLE III—DEVELOPMENT OF IMPROVED PHARMACEUTICALS AND OTHER THERAPEUTIC AGENTS

SEC. 301. PEDIATRIC STUDIES MARKETING EXCLUSIVITY.

Chapter V of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 501 et seq.) is amended by inserting after section 505 the following section:

''PEDIATRIC STUDIES FOR NEW DRUG APPLICATIONS

''SEC. 505A. (a) If an application submitted under section 505(b)(1) is approved on or after the date of enactment of this section, and such application includes reports of pediatric studies described and requested in subsection (c), and such studies are completed and the reports thereof submitted in accordance with subsection (c)(2) or completed and the reports thereof accepted in accordance with subsection (c)(3), the Secretary may not make the approval of an application submitted under section 505(b)(2) or section 505(j) which refers to the drug for which the section 505(b)(1) approval is granted effective prior to the expiration of 6 months from the earliest date on which the approval of such application for the drug under section 505(b)(2) or section 505(j), respectively, could otherwise be made effective under the applicable provisions of this chapter.

''(b) If the Secretary makes a written request for pediatric studies described in subsection (c) to the holder of an approval under section 505(b)(1) for a drug, and such studies are completed and the reports thereof submitted in accordance with subsection (c)(2) or completed and the reports thereof accepted in accordance with subsection (c)(3), the Secretary may not make the approval of an application submitted under section 505(b)(2) or section

505(j) which refers to the drug subject to the section 505(b)(1) approval effective prior to the expiration of 6 months from the earliest date on which an approval of such application under section 505(b)(2) or section 505(j), respectively, could otherwise be made effective under the applicable provisions of this chapter. Nothing in this subsection shall affect the ability of the Secretary to make effective a section 505(b)(2) or section 505(j) approval for a subject drug if such approval is proper under such subsection and is made effective prior to the submission of the reports of pediatric studies described in subsection (c).

''(c)(1) The Secretary may, pursuant to a written request for studies after consultation with the sponsor of an application or holder of an approval for a drug under section 505(b)(1), agree with the sponsor or holder for the conduct of pediatric studies for such drug.

''(2) If the sponsor or holder and the Secretary agree upon written protocols for such studies, the studies requirement of subsection (a) or (b) is satisfied upon the completion of the studies in accordance with the protocols and the submission of the reports thereof to the Secretary. Within 60 days after the submission of the report of the studies, the Secretary shall determine if such studies were or were not conducted in accordance with the written pro-

tocols and reported in accordance with the Secretary's requirements for filing and so notify the sponsor or holder.

''(3) If the sponsor or holder and the Secretary have not agreed in writing on the protocols for the studies, the studies requirement of subsection (a) or (b) is satisfied when such studies have been completed and the reports accepted by the Secretary. Within 90 days after the submission of the reports of the studies, the Secretary shall accept or reject such reports and so notify the sponsor or holder. The Secretary's only responsibility in accepting or rejecting the reports shall be to determine, within 90 days, that the studies fairly respond to the written request, that such studies have been conducted in accordance with commonly accepted scientific principles and protocols, and that such studies have been reported in accordance with the Secretary's requirements for filing.

''(4) As used in this section, 'pediatric studies' or 'studies' means at least 1 human clinical investigation in a population of adolescent age or younger. At the Secretary's discretion, pharmacokinetic studies may be considered as clinical investigations.

''(d) If the Secretary determines that an approval of an application under section 505(b)(2) or section 505(j) for a drug may be made effective after submission of reports of pediatric studies under this section but before the

Secretary has determined whether the requirements of subsection (c) have been satisfied, the Secretary may delay the effective date of any approval under section 505(b)(2) or section 505(j), respectively, until the determination under subsection (c) is made, but such delay shall not exceed 90 days. In the event that the requirements of this section are satisfied, the 6-month period referred to in subsection (a) or (b) shall be deemed to have begun on the date an approval of an application under section 505(b)(2) or section 505(j), respectively, would have been permitted absent action under this subsection.

''(e) The Secretary shall publish notice of any determination that the requirements of subsection (c)(2) or (c)(3) have been met and that approvals for the drug will be subject to deferred effective dates under this section.''.

○